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Mr. James E. Lyons
Director, New Reactor Licensing Project Office
Office of Nuclear Reactor Regulation
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

SUBJECT: Industry Comments on Draft ESP Review Standard (RS-002), Sections 15 and 17.1.1

PROJECT NUMBER: 689

Dear Mr. Lyons:

Attached are industry comments on two additional sections of the NRC staff's draft ESP Review Standard (RS-002) that were made available on April 14:

- Section 15, Radiological Consequences of Design Basis Accidents
- Section 17.1.1, Early Site Permit Quality Assurance Controls

These comments supplement those we provided on March 31 on the bulk of draft RS-002.

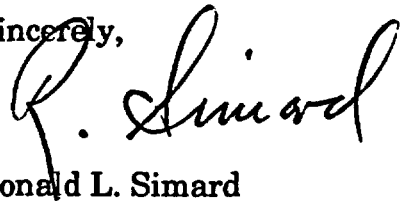
The attached comments reflect our disagreement with the staff identified in our April 10 letter on ESP-7 on the need for dose consequence analyses in ESP applications based on the plant parameters envelope approach, as well as our continuing concern for quality assurance inspections that focus on determining that ESP applicant quality controls are "equivalent in substance" to those of 10 CFR Part 50, Appendix B.

We have suggested changes to Section 17.1.1 consistent with the stated intent to assure that ESP applicant quality controls "provide reasonable assurance of the integrity and reliability of data that supports the site safety assessment and would be used as input in design or construction of SSCs important to safety." These changes are important to avoid the potential for time consuming and unproductive discussions regarding equivalence with Appendix B controls when the quality of the ESP information itself is either not in dispute or is readily verifiable.

We appreciate the NRC staff efforts to develop guidance for review of ESP applications, and the opportunity to provide input to the process.

If you have any questions about the enclosed comments on draft RS-002, Sections 15 and 17.1.1, please contact me (202-739-8128 or rls@nei.org) or Russ Bell (202-739-8087 or rjb@nei.org).

Sincerely,



Ronald L. Simard

Enclosure

c: Michael L. Scott, NRC/NRR
NRC Document Control Desk

Enclosure

Industry Comments on Draft ESP Review Standard RS-002, Sections 15 and 17.1.1

1. Section 15.I.2 – After the words "PPE values" in the third and fourth sentences, add the words, "and associated information in the ESP application." To determine site acceptability, the NRC staff will use the PPE in combination with associated information elsewhere in the ESP application.

2. Section 15.I.3 – This section is numbered incorrectly.

3. Section 15.I.3 – As is being demonstrated in connection with the pilot ESP applications, the full six-part NRC review of the radiological consequences of potential design basis accidents is not required to support NRC granting of an ESP. The guidance should be revised to reflect that it would be appropriate to perform the full six-part review only if sufficient design information is available and provided in the ESP application, and the ESP applicant requests an NRC determination that the criteria of 10 CFR 50.34(a)(1) are met for the specified combination of site and design.

4. Section 15.II, last paragraph – The exposure acceptance criteria specified in 10 CFR 50.34(a)(1) are required to be met at the COL stage. A lower acceptance criterion is not appropriate and should not be applied to ESP applications that do not reference an NRC certified design. Doing so will not provide reasonable assurance that 10 CFR 50.34(a)(1) will be met at COL because meeting the exposure acceptance criteria would remain strongly dependent on the plant design selected for the site. Also, applying a lower acceptance criterion would not be consistent with past NRC practice, e.g., a lower acceptance criterion was not applied during design certification reviews to account for siting uncertainties.

5. Section 15.III.1.4 – The guidance should indicate that staff re-confirmation that site-specific x/Q values are within those of the certified design referenced in a COL application is not necessary if this confirmation was accomplished in the ESP. In particular, this may be the case for an ESP that is based on a specific certified design and reflects the plant location on the site and fission product release points.

6. Section 15.III.1.5 – This item should be deleted. At the COL stage, if site-specific x/Q values are within those of the referenced certified design, no NRC review is required or appropriate to confirm that the criteria of 10 CFR 50.34(a)(1) are met. This is consistent with Section III.1.3, which states that, "If site-specific x/Q values are within those specified in the design certification, no further radiological consequence evaluation is needed."

7. Section 15.III.2.2 – The site-specific x/Q values are site characteristics, not PPE values.

8. Section 15.III.2.2 – As we identified in our April 10, 2003, letter on ESP-7, we disagree with the NRC staff that ESP applications must include dose consequence analyses. As described in our December 20, 2002, analysis of this issue (attached), providing dose consequence analyses is not necessary for compliance with Section 10 CFR 52.17(a)(1). The determination that radiological dose consequence criteria are met can only be made when both the site and design are known and interface issues can be evaluated. The pilot ESP applicants are using the PPE approach and have not specified a particular design as the basis for their applications. Thus the radiological consequence analyses that the pilot ESP applicants have been requested by the staff to provide will not yield a meaningful finding; design-specific analyses will be required to be submitted in any combined license application referencing the pilot ESPs.

   For an ESP application, the acceptability of the site with respect to Part 100 radiological dose consequence requirements and compliance with Section 52.17(a)(1) is dependent on the site characteristic χ/Q, including any assumptions on SSCs that bear significantly on the calculation of χ/Q such as elevated release point, and building locations associated with assumed wake effects. At COL, the site χ/Q is combined with the release history information provided in a design certification, or approved during the COL review of an uncertified design, to determine whether Part 100 requirements are met for the site/design combination.

   We note that at its March 7 meeting, the ACRS indicated strong support for this view, in particular that radiological dose consequence analyses in the absence of a specific design would not be meaningful and should not be required of ESP applicants.

   Pending final resolution of the differing industry and NRC staff views on this issue, to allow the ESP demonstration process to go forward, ESP applicants have indicated that they will provide radiological dose consequence analyses consistent with the draft review guidance to the extent design basis accident information is available for the designs on which the plant parameters envelope is based.

9. Section 15.III.2.3 – ESP applications based on the PPE approach, including the pilot applications, will not address the timing, nature and quantities of fission products released from the fuel to the containment. This information is not germane to the demonstration that the criteria of 10 CFR 50.34(a)(1) are met, or otherwise necessary to support required NRC staff reviews and findings for ESP.

Rather, this information is design-related and site-independent by nature and thus appropriately subject to NRC safety review in a design certification or combined license proceeding. Because ESP applications based on the PPE approach will not include this information, this review guidance should be deleted.

10. Add new Sections 15.III.2.7 and 15.III.2.8 as follows:

    15.III.2.7 – If a COL application references an ESP and a certified design, the staff reviews the site-specific x/Q values specified in the ESP to confirm that the site-specific x/Q values are within the bounds of those x/Q values provided in the reactor design certification based on the proposed plant design, the plant location on the site, and the fission product release points.

    15.III.2.8 – At the COL stage, in the event that the site-specific x/Q values exceed the bounds of those specified in a referenced design certification, the staff verifies that the applicant has demonstrated that the radiological consequences associated with the bounding DBAs using its site-specific x/Q values continue to meet the radiological consequence evaluation factors identified in 10 CFR 50.34(a)(1).

11. Section 15.IV.1 – The guidance should also reflect the scenario identified in Section 15.II.1.6. It is possible that x/Q values specified in the ESP will not be bounded by those of the certified design referenced, and that the COL application would contain additional analyses to support the determination that the acceptance criteria of 10 CFR 50.34(a)(1) are nonetheless met.

12. Section 17.1.1 – General Comment – We agree with the NRC staff that ESP applicants must implement quality controls "to provide reasonable assurance of the integrity and reliability of data that supports the site safety assessment and would be used as input in design or construction of SSCs important to safety." We believe that to verify the appropriate quality of ESP information, NRC inspections should focus on understanding the quality controls established by the ESP applicants and direct assessment of ESP information and its sources.

    For two reasons, we do not agree that NRC quality assurance inspections should focus on determining that the quality controls employed by ESP applicants are "equivalent in substance" to those of 10 CFR Part 50, Appendix B. First, as we have expressed in public meetings, our December 20, 2002, letter on ESP-3, and in comments on IMC-2501, Appendix B (or equivalent) controls are not necessary to assure the integrity and reliability of ESP information. And second, as the NRC staff has acknowledged, ESP applicants are not required to implement Appendix B or equivalent controls and are not

required to submit QA plans for NRC review. Thus it is inappropriate for NRC inspections to focus on whether or not an ESP applicant has quality controls that are equivalent to those of Appendix B.

We are concerned that undue focus on equivalence with Appendix B controls will result in time consuming and unproductive discussions of the adequacy of quality controls when the quality of the ESP information itself is either not in dispute or is readily verifiable.

We are heartened that the guidance states that "the staff will not base its regulatory finding on the ESP application solely on the equivalence of the applicant's QA controls to 10 CFR Part 50, Appendix B, controls." We offer specific comments below consistent with the intent to focus on assuring the integrity and reliability of ESP information.

13. Page 17.1.1-2, first full paragraph – We agree that NRC staff findings should be based on "whether or not the applicant has provided adequate controls to provide reasonable assurance of the integrity and reliability of data that supports the site safety assessment and would be used as input in design or construction of SSCs important to safety." We do not agree that "Therefore, any deviations of the applicant's QA controls from [controls equivalent to Appendix B] will be evaluated for their effect on the integrity and reliability of data supporting the ESP application." While we understand that Appendix B may be used by the staff as a guide, evaluating the effects of departures from Appendix B is inappropriate and unnecessary, especially when the integrity and reliability of ESP information is not in question.

    We have the same comment where this same language is used in the second paragraph under Section II on page 17.1.1-7.

14. Page 17.1.1-2, last paragraph – The second sentence should be revised as follows: "The regulations of 10 CFR 52.39 set forth an ESP process that has finality, in that the staff shall not revisit, absent significant new information, ~~should not need to revisit~~ site information as part of its review of a COL application.

15. Page 17.1.1-2, last paragraph – Modify the last sentence as follows: "Therefore, the staff plans to evaluate quality controls for activities associated with generation of ESP ~~this design~~ information to assure the controls are adequate to provide reasonable assurance of the integrity and reliability of the information ~~using the criterion that these controls be equivalent in substance to Appendix B to 10 CFR Part 50~~."

16. Page 17.1.1-3, third paragraph – Modify the last sentence as follows: "The scope of the review includes determination that the applicant has implemented quality controls that provide reasonable assurance of the integrity and reliability of data that supports the site safety assessment and would be used as input in design or construction of SSCs important to safety ~~of the equivalence between the applicant's proposed QA controls and the corresponding criteria of Appendix B to 10 CFR Part 50~~.

17. Page 17.1.1-3, fourth paragraph – Modify the last sentence as follows: In such cases, the NRC staff will evaluate the applicant's controls to assure they are adequate to provide reasonable assurance of the integrity and reliability of data that supports the site safety assessment and would be used as input in design or construction of SSCs important to safety ~~for adequacy, with the expectation that they will be equivalent in substance to those stated below~~.

18. Section I Quality Controls (pp. 17.1.1-3–7) – ESP applicants have established and implemented quality controls that provide for the integrity and reliability of ESP information. ESP applicant quality controls are not required to be equivalent to those of Appendix B, and, as indicated above, Appendix B or equivalent controls are not necessary to assure the integrity and reliability of ESP information. In particular, because of the limited scope of activities associated with ESPs, we do not agree that ESP applicants must establish controls, and be subject to equivalence reviews, in all 18 areas of Appendix B. Examples of Appendix B review areas that may not be germane to ESP activities include:

    - Criterion 8, "Identification and Control of Materials, Parts and Components"
    - Criterion 9, "Control of Special Processes"
    - Criterion 13, "Handling, Storage and Shipping"
    - Criterion 14, "Inspection, Test and Operating Status"
    - Criterion 15, "Nonconforming Materials, Parts or Components"

    The guidance in Section I should be revised to reflect that based on the limited scope of activities performed for ESP, applicants need not have quality controls in place in all 18 areas of 10 CFR Part 50, Appendix B.

19. Page 17.1.1-7, first paragraph under Section II – Modify the third sentence as follows: The applicant is expected to demonstrate that quality controls ~~equivalent in substance to 10 CFR Part 50, Appendix B,~~ have been implemented that provide reasonable assurance of the integrity and reliability of data that supports the site safety assessment and would be used as input in design or construction of SSCs important to safety.

20. Page 17.1.1-7, second paragraph under Section II – Same comment as Comment 13, above.

21. Section II Acceptance Criteria (pp. 17.1.1-7–21) – As stated earlier, it is not appropriate to establish acceptance criteria for the purpose of determining that ESP applicant quality controls are equivalent to those of 10 CFR Part 50, Appendix B. This is because Appendix B or equivalent controls are not necessary to assure the integrity and reliability of ESP information, and ESP applicants are not required to implement Appendix B or equivalent controls.

    In particular, the NRC staff should not perform reviews for conformance with acceptance criteria in areas of Appendix B that are not applicable due to the limited scope of ESP applicant activities (see previous comment).

    Even in Appendix B areas expected to be addressed by ESP applicant quality controls, Section II includes acceptance criteria that may not be applicable or appropriate based on the nature of the ESP applicant's organization and the limited scope of ESP activities. We believe many of these have no applicability to assuring the integrity and reliability of ESP data and should be eliminated from RS-002.

    At minimum, the guidance should be modified to reflect that based on the nature of the ESP applicant's organization and the limited scope of ESP activities, applicants need not have quality controls in place in all 18 areas of 10 CFR Part 50, Appendix B, and that not all of the acceptance criteria identified in Section 17.1.1 may be applicable and appropriate for review. Moreover, we recommend that NRC quality-related inspections and associated acceptance criteria focus on performance-based assessment of ESP data and its actual handling, rather than on review of ESP applicant quality controls for equivalence to Appendix B.

Attachment to NEI June 13 Comments on Draft RS-002
Analysis of Section 52.17(a)(1) Compliance
for ESP Applications Under the PPE Approach

1. Pertinent NRC Regulations:

- Section 52.17(a)(1) states in part:

> "...The application must also contain a description and safety assessment of the site on which the facility is to be located. The assessment must contain an analysis and evaluation of the major structures, systems, and components of the facility that bear significantly on the acceptability of the site under the radiological consequence evaluation factors identified in Section 50.34(a)(1) of this chapter. Site characteristics must comply with Part 100 of this chapter."

- Similarly, 10 CFR 100.21(c)(2) requires site atmospheric dispersion characteristics be evaluated and dispersion parameters established such that:

> "Radiological dose consequences of postulated accidents shall meet the criteria set forth in Section 50.34(a)(1) of this chapter for the type of facility proposed to be located at the site."

- Lastly, the radiological consequence evaluation factors identified in Section 50.34(a)(1) are as follows:

> (ii)(D)(1) An individual located at any point on the boundary of the exclusion area for any 2 hour period following the onset of the postulated fission product release, would not receive a radiation dose in excess of 25 rem total effective dose equivalent (TEDE) (footnote omitted).
>
> (2) An individual located at any point on the outer boundary of the low population zone, who is exposed to the radioactive cloud resulting from the postulated fission product release (during the entire period of its passage) would not receive a radiation dose in excess of 25 rem total effective dose equivalent (TEDE).

2. Discussion:

Compliance with the radiological dose consequence criteria in Sections 100.21 and 50.34(a)(1) for postulated accidents is a requirement under Subpart A, Early Site Permits, Subpart B, Standard Design Certification, and Subpart C, Combined

Licenses. As indicated below, elements of this requirement can be addressed as part of ESP and DC, however, the determination that radiological dose consequence criteria are met can only be made at COL when both the site and design are known and interface issues can be evaluated.

- An ESP application determines the atmospheric dispersion characteristics for a particular site (i.e., the site characteristic associated with Part 100 compliance)

- A standard design certification application postulates site atmospheric dispersion characteristics (χ/Q) for an unspecified generic site and calculates radiological dose consequences associated with the structures, systems and components of the particular design (i.e., design characteristics associated with Part 100 compliance). This calculation demonstrates that any site with a χ/Q equal to or conservative with respect to the postulated χ/Q, will have dose consequences that meet Section 50.34(a)(1) for the design being certified.

- A Combined License application integrates the χ/Q for a particular site with the design characteristics for the specified plant and may do so via reference to an ESP and/or a DC. If an ESP and DC are referenced, the applicant must provide information sufficient to demonstrate that the design of the facility falls within the parameters specified in the early site permit [Section 52.79(a)(1)]. If the postulated χ/Q in the design certification falls within the actual χ/Q in the early site permit, the specific reactor/site combination meets the radiological consequence evaluation factors identified in Sec. 50.34(a)(1). If the postulated χ/Q does not fall within the actual χ/Q, compliance with the radiological criteria must be demonstrated in the combined license application.

3. Compliance with Section 52.17(a)(1):

As explained above, compliance with the radiological dose consequences in Sec. 50.34(a)(1) as referred to by Sec. 52.17(a)(1) and Sec. 100.21(c)(2) is determined by the integration of the evaluations performed in the early site permit, standard design certification, and combined license applications.

52.17(a)(1) also states that the ESP safety assessment "must contain an analysis and evaluation of the major structures, systems, and components of the facility that bear significantly on the acceptability of the site under the radiological consequence evaluation factors identified in Section 50.34(a)(1)..."

The calculated dose consequences of postulated accidents is dependent on χ/Q (a site characteristic) and release history (a design characteristic):

- Chi/Q is a function of radiological release point, building wake effects, distance to exclusion area boundary and low population zone boundary, historical meteorological data associated with the site, and atmospheric dispersion models.

- Release history is a function of source term, containment characteristics, filtration system characteristics, other mitigation system characteristics, release timing, and accident type.

For an Early Site Permit application, the acceptability of the site is dependent on the site characteristic of χ/Q, including any assumptions on SSCs that bear significantly on the calculation of χ/Q such as elevated release point, and building locations associated with assumed wake affects. Based on NRC guidance for calculating χ/Q, we expect that for most ESP applicants, there will be no such dependencies on SSCs that affect the calculation of χ/Q. This is true of the pilot ESP applicants, who, consistent with applicable guidance in RG 1.145 for calculating χ/Q, are each assuming ground level releases with no wake effects.

For a standard design certification application, the acceptability of the design is dependent on the release history, including any assumptions on SSCs inherent in the calculation of the release history. The accompanying dose calculations postulate a site χ/Q which will be compared with an actual site characteristic in a combined license application.

If an ESP application includes release history information for a certified standard design, the integration of χ/Q with release history information and the determination that the specified site/design combination meets Part 100 requirements may be accomplished at ESP.

For a combined license application, the acceptability of the site/design combination (i.e., meeting Part 100 requirements) is dependent on the site χ/Q in the ESP and the release history for the selected design. If the site χ/Q is conservative with respect to that assumed in a referenced design certification, then the site/design combination meets Part 100 requirements.

4. Summary:

Chi/Q is the site characteristic associated with meeting Part 100 radiological dose consequence requirements, and compliance with Sec. 52.17(a)(1) in the ESP application is accomplished by determining the site χ/Q, including the effect of SSCs, if any, that bear significantly on that result. At COL, the site χ/Q is combined with the release history information provided in a design certification, or approved during the COL review of an uncertified design, to determine whether Part 100 requirements are met for the site/design combination.